

The Office Action rejects claims 1-5 under 35 U.S.C. 102(b) as being anticipated by Ref U (Kim et al, AN 1998:101607), Ref V (OITA ET AL 1985:427328, Ref W (CAPLUS 1991:115063), or REF X (LUC ET AL 1993:168134). The Office Action states:

Each of the references is considered to be within the scope of the broad claimed language in view of the following decision:

"It is well settled that if a reference reasonably teaches a product which is identical or substantially identical or are produce by identical or substantially identical process, the PTO can require an applicant to prove that the prior art products do not inherently possess the characteristics of his claimed product. A rationale given for shifting the burden of going forward to applicant is that the PTO does not possess the facilities to manufacture or to obtain and compare prior art products, see *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972); *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977)."

The rejection of the claims will be maintained absent a showing that the compositions of the references are not within the scope of the claimed products. It is acknowledged that the references do not have the claimed use but a new use for an old composition is not patentable in this particular application.

Office Action at pages 3-4. Applicant respectfully traverses this rejection.

The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention under any statutory provision always rests on the PTO. *In re Mayne*, 104 F.3d 1339, 41 USPQ2d 1451 (Fed. Cir. 1997); *In re Oetiker*, 977 F. 2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). Applicants respectfully submit that the Office Action has not discharged this initial burden. The factual determination of lack of novelty under 35 U.S.C. § 102 requires the identical disclosure in a single reference of each element of a claimed invention. *The Kegel Co. v. AMF Bowling*, 127 F.3d 1420, 44 USPQ2d 1123 (Fed. Cir. 1997); *Gechter v. Davidson*, 116 F.3d 1454, 43 USPQ2d 1030 (Fed. Cir. 1997). In rejecting a claim under 35 U.S.C. §102, the PTO is required to identify wherein a particular reference identically discloses each feature of the

claimed invention. *In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). There are significant differences between the presently claimed invention and the cited references. To whatever extent the imposed rejections are predicated upon the doctrine of inherency, such reliance is totally misplaced. Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. See *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159, 47 USPQ2d 1829, 1834 (Fed. Cir. 1998) ("In order for a disclosure to be inherent . . . the missing descriptive matter must necessarily be present in the . . . application's specification such that one skilled in the art would recognize such a disclosure."). Inherency is not a matter of hindsight based on the applicant's disclosure: the missing claim elements must necessarily be present in the prior art. Since the claimed invention is not described in a single prior art reference, it is not "anticipated."

In particular, the claimed invention is directed to a pharmaceutical composition for the prevention or treatment of **soft tissue cancer** in mammals, comprising at least one plant essential oil compound. The written description and Examples provide ample support for the claimed invention. None of the cited references disclose compositions against cancer. Indeed, these references are conspicuously mute as to the fundamental concept of treating or preventing cancer. This fundamental difference alone between the claimed invention and the cited references is sufficient to undermine the factual determination of lack of novelty under 35 U.S.C. §102. See *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 230 USPQ 81 (Fed. Cir. 1986). It is well settled that the doctrine of inherency requires **both certainty and art recognition**. *In re*

Paulsen, 30 F.3d 1475, 31 USPQ2d 167 (Fed. Cir. 1994); *Electro Medical Systems S.A. v. Cooper, Life Sciences, Inc.* 34 F.3d 1048, 32 USPQ2d 1017 (Fed. Cir. 1994). It is not apparent, and the PTO has not identified, wherein these cited references lies a disclosure of the activity of the presently claimed composition. The requirement for certainty coupled with art recognition is not satisfied by Ref U (Kim et al, AN 1998:101607), Ref V (OITA ET AL 1985:427328, Ref W (CAPLUS 1991:115063), or REF X (LUC ET AL 1993:168134), as cited and tenuously applied by the Examiner, alone or in combination. Thus, there is no basis upon which to predicate the determination that the use of plant essential oils, let alone eugenol, in accordance with the teachings of Ref U (Kim et al, AN 1998:101607), Ref V (OITA ET AL 1985:427328, Ref W (CAPLUS 1991:115063), or REF X (LUC ET AL 1993:168134) necessarily involves the treatment or prevention of cancer, and that such would have been recognized by one having ordinary skill in the art. Accordingly, there is no basis upon which to invoke the doctrine of inherency. The bottom line is that the applied references, taken singly or in any combination, do not disclose or suggest the presently claimed invention. Applicants, therefore, respectfully submit that the imposed rejection of claims 1-5 under 35 U.S.C. § 102(b) predicated upon the cited references is not factually or legally viable to shift the burden of proof and, hence, solicit reconsideration and withdrawal thereof.

Early consideration and prompt allowance of the pending claims are respectfully requested. If anything could be done to place this application in condition for allowance, e.g., by **Examiner's Amendment**, Applicants respectfully request that the Examiner contact the undersigned representative at the telephone number listed below.

Please grant any extension of time deemed necessary for entry of this communication.

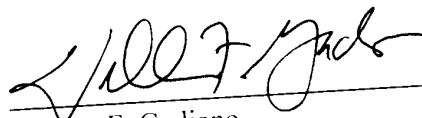
Please charge any deficient fees, or credit any overpayment of fees, to Deposit Account No.

50-0417.

Respectfully submitted,

Date: July 22, 2001

By:



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